

REMARKS

Support for Amendments

Support for the amendment to claim 1 is found in the specification at page 13, lines 20-23. Support for the amendment to claim 6 is found at page 3, lines 19-24 and page 13, lines 23-31. No new matter is introduced by these amendments.

A "marked up" version of the claims showing the changes made and an appendix of the claims as pending are attached.

The Office Action

Claims 1-12 are pending in this application. Claims 1-12 stand rejected under 35 U.S.C. § 112 for both lack of enablement and indefiniteness. Claims 1-12 stand further rejected under 35 U.S.C. § 102(b) for anticipation by Wilson *et al.* (U.S. Patent No. 5,703,047). Each of these rejections is addressed individually below.

Rejections Under 35 U.S.C. § 112

Lack of Enablement

All pending claims stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that, while being enabling for a method of enhancing corneal epithelial wound healing, it does not provide enablement for treatment of the associated inflammation of the disorders listed in the claims. Further, the Examiner notes that the claims are not limited to a direct contacting of the eye with the trefoil peptide.

In response, Applicant points out that the claims have been amended to recite treating a disruption of the corneal epithelium (i.e., a corneal epithelial wound). Furthermore, claim 1, as presently amended, requires that the trefoil protein is administered "to the eye of said patient." Accordingly, Applicant respectfully requests withdrawal of this rejection.

Indefiniteness

All pending claims stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Specifically, the Examiner asserts that the phrase "treatment of an eye disorder characterized by an injury to the corneal epithelial" does not recite what aspect of the disorder is positively affected by trefoil protein therapy.

Applicant overcomes this rejection by amendment. As noted previously, the claims have been amended to read on a method for treating a disruption of the corneal epithelium. Accordingly, this rejection may be withdrawn.

Rejections Under 35 U.S.C. § 102(b)

All pending claims are rejected under 35 U.S.C. § 102(b) in view of Wilson et al. (U.S. Patent No. 5,703,047). Specifically, the Examiner asserts that the use of epidermal growth factor (EGF), as described by Wilson, falls within the scope of the claims of the instant application. In view of the present claim amendments, Applicant respectfully requests this rejection be withdrawn.

CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Version With Markings to Show Changes Made

In the Claims:

1. (Twice Amended) A method for the treatment of [an eye disorder] a disruption of the corneal epithelium in a patient, [said disorder characterized by an injury to the corneal epithelial,] said method comprising administering to the eye of said patient a trefoil protein selected from the group consisting of intestinal trefoil factor (ITF), spasmolytic peptide (SP), pS2, and [or a] biologically active fragments [fragment] thereof.

3. (Amended) The method of claim 2, wherein said trefoil protein is intestinal trefoil factor [peptide] (ITF).

6. (Amended) The method of claim 1, wherein said disorder is [a superficial punctate keratitis,] a corneal ulcer, [a herpes simplex keratoconjunctivitis, an ophthalmic herpes zoster, a phlyctenular keratoconjunctivitis, a keratoconus, a conjunctiva, a keratoconjunctivitis sicca (dry eyes), an ocular inflammation, a corneal ulcer or a cicatricial penhigoid] or is caused by a traumatic physical injury, eye surgery, a chemical exposure, or an ultraviolet light exposure.

12. (Amended) The method of claim 1 [7], wherein administration is topical.